

APR 30 2004

510(k) Summary
Quantum Cement Restrictor

510(k) Number K040276

Manufacturer Identification

Submitted by:

Quantum Orthopedics, Inc.
32896 Saint Moritz Drive
Evergreen, CO 80439
303-679-8895

Contact Information:

Jason Blain
Chief Technology Officer
Quantum Orthopedics, Inc.
11662 Corte Guera
San Diego, CA 92128
858-451-8698
jblain@quantumorthopedics.com

Date Prepared:

February 4, 2004

Device Identification

Proprietary Name:

Quantum Cement Restrictor

Common Name:

Cement Restrictor

Classification Name:

Surgical Mesh/Prosthesis, Hip, Cement Restrictor

Predicate Devices

The subject device is substantially equivalent to previously cleared devices.

Device Description

The Quantum Cement Restrictor is a generally box-shaped device with various holes located throughout its geometry to hold bone cement. The exterior surface of the device has teeth to help keep the device from migrating once placed in its desired location. It is available in a multitude of sizes to suit the individual pathology and anatomic condition of the patient. The device may be made from titanium, polyetheretherketone (PEEK), or ceramic materials.

page 1 of 2

Intended Use of the Device

The Quantum Cement Restrictor is indicated for use as a cement restrictor in the femur, tibia, or humerus.

This device is not intended for spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established

Substantial Equivalence

The Quantum Cement Restrictor was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2004

Mr. Jason Blain
Chief Technology Officer
Quantum Orthopedics, Inc.
11662 Corte Guera
San Diego, California 92128

Re: K040276
Device Name: Quantum Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: February 4, 2004
Received: February 6, 2004

Dear Mr. Blain:

We have reviewed your Section 510(k) pre-market notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

**THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN
IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.**

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

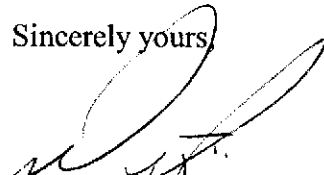
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Daniel G. Schultz, M.D.

Director

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040276

Device Name: Quantum Cement Restrictor

Indications For Use:

The Quantum Cement Restrictor is indicated for use as a cement restrictor in the femur, tibia, or humerus.

This device is not intended for spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.

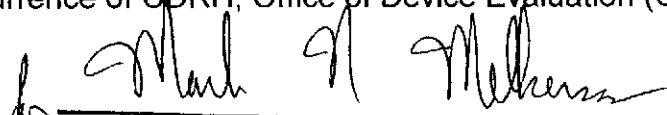
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040276

Page 1 of 1